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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LUCAS JOHANNES ANNA MARIA BECKERS, REMCO VIRGIL WOEN, and JOOST HUBERT MAAS

Appeal 2016-001894 Application 13/148,070 Technology Center 1600

Before JEFFREY N. FREDMAN, RICHARD J. SMITH, and DAVID COTTA, *Administrative Patent Judges*.

FREDMAN, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal¹ under 35 U.S.C. § 134 involving claims to a microfluidic system. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

Statement of the Case

Background

"The biotechnology sector has directed substantial effort toward developing miniaturized microfluidic devices, often termed labs-on-a-chip (LOC) or micro total analysis systems, (micro-TAS), for sample

¹ Appellants identify the Real Party in Interest as Koninklijke Philips Electronics N.V. (*see* App. Br. 1).

manipulation and analysis" (Spec. 1:10–12). "Integrated microfluidic devices need to combine a number of functions, like filtering, mixing, fluid actuation, valving, heating, cooling, and optical, electrical or magnetic detection, on a single template" (Spec. 1:18–20).

The Claims

Claims 1–3, 5–7, and 9–15 are on appeal. Claims 1 and 15 are representative and read as follows:

- 1. A microfluidic system, comprising a substrate having a surface with at least one micro channel structure thereon, the substrate comprising a uniform rubber material which comprises polar side groups, wherein each of the polar side groups is linked with the polymer chain of said rubber material via a linker comprising at least 6 atoms, wherein the content of said polar side groups is ≥ 0.01 and ≤ 1 mol per 100 g rubber material.
- 15. A microfluidic system, comprising a substrate having a surface with at least one micro channel structure formed in an injection moldable rubber material which comprises polar side groups, wherein each of the polar side groups is linked with the polymer chain of said rubber material via a linker comprising at least 6 atoms, wherein the content of said polar side groups is ≥0.01 and ≤1 mol per 100 g rubber material.

The Issues

A. The Examiner rejected claims 1, 3, 6, 11, 12, and 15 under 35 U.S.C. § 103(a) as obvious over Huang,² Sibarani,³ and Dow Corning⁴ (Final Act. 3–9).

² Huang et al., US 2002/0160139 A1, published Oct. 31, 2002 ("Huang").

³ Sibarani et al., Surface Modification on Microfluidic Devices with

- B. The Examiner rejected claims 2, 9, and 10 under 35 U.S.C. § 103(a) as obvious over Huang, Sibarani, and Bodas⁵ (Final Act. 9–11).
- C. The Examiner rejected claim 5 under 35 U.S.C. § 103(a) as obvious over Huang, Sibarani, and Wang⁶ (Final Act. 11–12).
- D. The Examiner rejected claims 7, 13, and 14 under 35 U.S.C. § 103(a) as obvious over Huang, Sibarani, and Park⁷ (Final Act. 12–14).
- A. 35 U.S.C. § 103(a) over Huang and Sibarani

The Examiner finds that Huang teaches:

a microfluidic system . . . comprising (i) A substrate having a surface with at least one channel or flow channel . . . (ii) whereby at least a part of said substrate comprises an elastomeric material, such as silicones, nitrile rubbers, siloxanes and/or styrenebutadiene . . . (iii) which comprises "surface modifying compounds" . . . (i.e., polar side groups); (iv) whereby the surface modifying compounds are attached to the polymer via a "reactive" or "intrinsic" functional group . . . i.e., each of the polar side groups is linked with the polymer chain.

²⁻Methacryloyloxyethyl Phosphorylcholine Polymers for Reducing Unfavorable Protein Adsorption, 54 Colloids and Surfaces B: Biointerfaces 88–93 (2007) ("Sibarani").

⁴ Dow Corning, Rubber Fabrication Processes, http://www.dowcorning.com/content/rubber/rubberprocess/ (Accessed Jan. 9, 2014) ("Dow Corning").

⁵ Bodas et al., Fabrication of Long-Term Hydrophilic Surfaces of Poly(Dimethyl Siloxane) Using 2-Hydroxy Ethyl Methacrylate, 120 Sensors AND ACTUATORS B 719–23 (2007) ("Bodas").

⁶ Wang et al., Sulfonated-Polydimethylsiloxane (PDMS) Microdevices with Enhanced Electroosmotic Pumping and Stability, 84 CANADIAN J. CHEMISTRY 720–29 (2006) ("Wang").

⁷ Park et al., A Large-Deflection High-Force Micro Electromagnetic Hydraulic Latex Membrane Actuator For Fluid Manipulation In Micro Channels, MEMS 2011 1209–12 (2011) ("Park").

(Ans. 3–4). The Examiner acknowledges that Huang does "not explicitly disclose a rubber material with polar side groups" linked "via a linker comprising at least 6 atoms" (Ans. 4) and does not "disclose wherein the content of said polar side groups is >=0.01 and <=1 mol per 100g rubber material" (Ans. 5).

The Examiner does find that Huang exemplifies elastomeric materials "connected via said functional groups, which are comprised of at least 6 atoms" (Ans. 4). The Examiner finds it obvious "to select an elastomeric material, intrinsic functional groups and surface modification compounds to make a final material with properties desirable for use in a microfluidic device" because "[a]lternative species listed in a prior art reference motivates and/or suggests utilizing any alternative therein as functional equivalents and thus are obvious variants" (Ans. 4).

The Examiner finds Sibarani teaches a compound "wherein the content of said polar side groups is >=0.01 and <=1 mol per 100g rubber material" (Ans. 5). The Examiner finds the amount of Sibarani obvious because Huang teaches "selecting the ratio of components to combine in order to generate the proper surface characteristics for a microfluidic device" (Ans. 6).

The issue with respect to these rejections is: Does the evidence of record support the Examiner's conclusion that Huang and Sibarani suggest a microfluidic system with a substrate comprising a "uniform rubber material" as required by claim 1 and a "micro channel structure formed in an injection moldable rubber material" as required by claim 15?

Findings of Fact

- 1. The Specification teaches that "the rubber material may be present as a uniform material or a block or graft polymer" (Spec. 8:13–14).
 - 2. The Specification teaches an example where:

The manufacturing procedure of Elastosil® LR 3003/60 US was altered as follows.

Silicone component A, containing vinyl groups on the Siloxane chain, with platinum catalyst, was high speed mixed with Sodium alkene (C14-C16) sulfonate. After mixing, the mixture was heated up to 120 degrees Celsius and mixed again.

After cooling down at room temperature, to room temperature, Silicone component B was added. Component B comprises Hydro-Silicon bondings which function as a cross-linker. The two components are high speed mixed again. The mixture was prepared in a cartouche which could be used to feed the injection molding equipment. The cartouche was held under pressure for constant feeding.

Injection molding occurred in a mold for shaping the fluidic devices

(Spec. 12:14-24).

3. The Specification teaches "in the context of the present invention it is not necessary that the entire substrate is made out of the inventive rubber material, although this is *ad libitum* for the skilled person in the art and a preferred embodiment of the present invention" (Spec. 3:23–26).

4. The Specification teaches

the term "rubber material" especially includes and/or means an elastomeric material. Examples of suitable materials which may be used in the context of this invention are: . . . EPDM ethylene-propylene-diene copolymers, ESBR styrene-butadiene copolymers, CR polychloroprene, BR polybutadiene . . . Q

silicone rubbers, AU polyester urethane polymers, EU polyether urethane polymers

(Spec. 3:30 to 4:25).

5. Huang teaches:

Exemplary off-ratio polymers include, but are not limited to, silicone RTV, polyurethane. . . . Exemplary, pre-crosslinked polymers include, but are not limited to, any vinyl containing elastomer systems, such as, poly(isobutylene isoprene), poly(styrene butadiene), poly(isoprene), poly(butadiene), polychloroprene, vinyl containing rubber gums that can be formulated and milled, etc.

(Huang ¶ 108).

- 6. Huang teaches "a microfluidic device. Preferably, the channel defines a fluid flow channel of the microfluidic device" (Huang ¶ 25).
- 7. Huang teaches "polymers having hydrophilic surfaces can be produced by using a surface modifying compound such as polyvinylpyrrolidone, PVA, PEG, and the like" (Huang ¶ 128).
 - 8. Figure 2 of Huang is reproduced in part below:

Silicone surface modification route III:

Sep 1.

$$\begin{pmatrix}
H \\
Si - O \\
CH_{3}
\end{pmatrix} + CH_{2} = CH - R \implies \begin{pmatrix}
H \\
Si - O \\
CH_{3}
\end{pmatrix} \begin{pmatrix}
CH_{2}CH_{2}R \\
Si - O \\
CH_{3}
\end{pmatrix} y \gg x$$
Sep 2.

$$\equiv Si - CI = CH_{2} + \begin{pmatrix}
H \\
Si - O \\
CH_{3}
\end{pmatrix} \begin{pmatrix}
CH_{2}CH_{2}Si - O \\
CH_{3}CH_{2}Si - O \\
CH_{3$$

Figure 2

The "third method[] of FIG. 2 illustrate[s] formation of a silicon-alkyl bond by reacting silane with an olefin" (Huang ¶ 134).

9. Sibarani teaches "we modified conventional polymer materials' surfaces including PDMS by simply coating with the MPC polymers and investigated the effects of modified polymers on the protein adsorption" (Sibarani 89, col. 1).

10. The Examiner finds

Sibarani et al. disclose wherein the content of said polar side groups is >=0.01 and <=1 mol per 100g rubber material. The molecular weight of the PDMS of Sibarani et al . . . is 163g/mole, excluding the end-group, for a n=1 monomeric unit. Molecular weight increases to 236g/mole with inclusion of the end-group. The analysis which follows works for either value, but 163g/mole is used. The -NR1 R2R3+ polar side group of MDC is comprised of (N) + (CH3)3 = 59g/mole. Claim 1 of the instant application recites a limitation drawn to the following range of values for the content of the polar side group: >=0.01 mole (or 0.59g) and <=1 mole (or 59g) per 100g/rubber material (i.e., PDMS). 100g of PDMS = 0.6135 moles. According to Huang et al., the ratio of the reactive functional group (i.e., polar side groups) to the bulk polymer (i.e., PDMS) is preferably ≥ 1 to 100 ([0109]). In other words, ≥ 1 functional group per 100 monomeric units of PDMS. Converted to moles, this can be restated as: >=1 mole per 100 moles. For example, 10 moles of -NR1 R2R3+ per 100 moles PDMS falls within the scope of the limitation of Claim 1 of the instant application (e.g., 0.0635 moles of -NR1 R2R3+ per 0.6135 moles, or 100g, of PDMS) and, therefore, is taught by Huang

(Ans. 5–6).

Principles of Law

Claim terms are interpreted using the broadest reasonable interpretation in light of the Specification. *See, e.g., In re Hyatt*, 211 F.3d

1367, 1372 (Fed. Cir. 2000) ("[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.").

Analysis

We begin with claim interpretation because before a claim is properly interpreted, its scope cannot be compared to the prior art. In this case, the dispute centers over the term "uniform" in claim 1 and "micro channel structure formed in an injection moldable rubber material" in claim 15.

Claim 1

The Specification teaches that "the rubber material may be present as a uniform material" (FF 1) and exemplifies a process where the rubber material and polar side group materials are combined by high speed mixing (FF 2). The Specification recognizes that mixed materials are possible, but prefers "that the entire substrate is made out of the inventive rubber material" (FF 3).

Therefore, reading the term "uniform" in light of the Specification, we interpret "uniform" to require that the material is compositionally uniform and requires a first rubber material mixed together with a polar material to form a compositionally uniform material, not simply coated with the polar material.

Appellants agree, stating "Appellant disclaims from the claim scope of claim 1 a rubber material that is not compositionally uniform. That is, the term 'uniform' is clearly and unmistakably defined herein to mean 'compositionally uniform'" (App. Br. 10).

We recognize, but find unpersuasive, the Examiner's finding that Appellants recitation of "comprising multiple times in claim 1 leaves open the door for the exact combination of references as have been cited above. That is, as the Examiner reads claim 1, claim 1 allows for the compositionally uniform rubber of Huang et al. WITH the polar side groups of Sibarani" (Ans. 15).

While the Examiner is correct that the term "comprising" permits the substrate to have a coating of a material with polar side groups, claim 1 requires that the uniform rubber material itself "comprises polar side groups". Thus, as we already discussed, the "uniform rubber material which comprises polar side groups" must be a compositionally uniform material with polar side groups present throughout the material, not simply coated on top. While an additional coating would be encompassed by the claims as noted by the Examiner (*see* Ans. 15), the evidence of record does not establish that Huang and Sibarani render a "uniform rubber material which comprises polar side groups" obvious where the material is compositionally uniform.

Claim 15

We interpret the phrase "micro channel structure formed in an injection moldable rubber material" in claim 15 to require the presence of a micro channel structure in the rubber material.

Appellants acknowledge that "Huang discloses a conventional rubber material that is injection moldable" (App. Br. 9), but contend that "[w]hile the surface of Huang's device may be surface modified to include polar groups, the surface features themselves are clearly not 'formed in an

injection moldable rubber material which comprises polar side groups" (*Id.* at 8).

We do not find this argument persuasive because claim 15 is drawn to an apparatus, not a method for forming a substrate, and because claim 15 does not require a "uniform" material as in claim 1. "In determining validity of a product-by-process claim, the focus is on the product and not the process of making it." *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1369 (Fed.Cir.2009). The process of making is only relevant "if the process by which a product is made imparts 'structural and functional differences' distinguishing the claimed product from the prior art" *Greenliant Systems, Inc. v. Xicor LLC*, 692 F.3d 1261, 1268 (Fed. Cir. 2012).

Here, Appellants do not identify any structural or functional differences that result from the process of injection molding relative to the microfluidic device with microchannels rendered obvious by Huang and Sibarani (FF 5–10).

We recognize, but find unpersuasive, Appellants' contention that "At no point in Huang's *process* does he produce a material having polar side groups that is injection moldable" (App. Br. 9; emphasis added). The weight of authority holds that the patentability of product-by-process claims is not dependent on process limitations. *See In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) ("even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself;" "[t]he patentability of a product does not depend on its method of production;" and "[i]f the product in a product-by-process claim is the same

as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.")

We recognize, but find unpersuasive, Appellants' contention that "a polymer having polar side groups that is compositionally uniform is produced and handled in a bulk fashion, and once made, is injection molded in an exemplary embodiment of Appellant's specification" (App. Br. 10). Claim 15 lacks any requirement for a "uniform" or compositionally uniform material, but simply requires a material that "comprises polar side groups", reasonably encompassing the coated material rendered obvious by Huang and Sibarani.

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that Huang and Sibarani suggest a microfluidic system with a substrate comprising a "uniform rubber material" as required by claim 1.

The evidence of record supports the Examiner's conclusion that Huang and Sibarani suggest a "micro channel structure formed in an injection moldable rubber material" as required by claim 15.

B-D. 35 U.S.C. § 103(a)

These rejections rely upon the underlying obviousness rejection over Huang and Sibarani over claim 1. Having reversed the rejection over claim 1, we also necessarily reverse the further obviousness rejections over dependent claims.

SUMMARY

We reverse the rejection of claims 1, 3, 6, 11, and 12 under 35 U.S.C. § 103(a) as obvious over Huang, Sibarani, and Dow Corning.

We affirm the rejection of claim 15 under 35 U.S.C. § 103(a) as obvious over Huang, Sibarani, and Dow Corning.

We reverse the rejection of claims 2, 9, and 10 under 35 U.S.C. § 103(a) as obvious over Huang, Sibarani, and Bodas.

We reverse the rejection of claim 5 under 35 U.S.C. § 103(a) as obvious over Huang, Sibarani, and Wang.

We reverse the rejection of claims 7, 13, and 14 under 35 U.S.C. § 103(a) as obvious over Huang, Sibarani, and Park.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART